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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/077,283 | 02/14/2002 | Matthias Rath | 11957/20 | 3317 |
| 26646 | 7590 | 10/08/2004 | EXAMINER | |
| KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004 | | | MARX, IRENE | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1651 | |

DATE MAILED: 10/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/077,283

Applicant(s)

RATH, MATTHIAS

Examiner

Irene Marx

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-7 and 10-26 is/are pending in the application.
- 4a) Of the above claim(s) 4-7, 10-22 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 23-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The application should be reviewed for errors and conformity with domestic practice. Error occurs, for example, in the spelling of "bionenergy" in claims 23-25. Error also occurs in the spelling of "oxalsuccinate" and "oxalacetate". The accepted designation is "oxalosuccinate" and "oxaloacetate". Correction is recommended.

The amendment filed 8/20/04 is acknowledged. Claims 1 and 23-25 are being considered on the merits.

Claims 4-7, 10-22 and 26 are withdrawn from consideration as directed to a non-elected invention. Please note that newly presented claim 26 is directed to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 23-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for the designation as "substances of Krebs cycle" at least for the following: oxalsuccinate, lipoic Acid, lipoamide, acetyl-lipoamide, lysine, carnitine, niacinamide, pantothenate, quinolate, ascorbate, copper iron-sulfate and molybdenum (See, e.g., Figure 1, Krebs Cycle; specification, page 6).

No basis or support is found in the present specification for the recited amounts/day as required in new claims 23-25 (See, e.g., Specification, page 6).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1 and 23-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 23-25 are vague and indefinite in the recitation “ wherein the composition **is in the form of pharmaceutically acceptable carriers for consumption...**”. (emphasis added). It is unclear what is intended by “in the form of ... carriers for consumption”. Generally carriers are added to pharmaceutically active compounds. Confusion is compounded by 1) the further recitation of “injections, inhalations, suppositories” which are clearly not in the category of “for consumption”, unless the treatment of tuberculosis is intended; and 2) the further recitation of “or other pharmaceutically acceptable carriers and/or means of delivery”. The correlation between “in the form of a carrier” and “means of delivery” cannot be readily ascertained in this context.

In addition it is unclear which clauses are intended to be modified by “or other pharmaceutically acceptable carriers”, respectively, “and/or means of delivery”. Clarification is recommended.

Claims 23-25 are confusing in the recitation of a composition consisting essentially of an amount/day in a broad range of 0.001-100 mg for each of the compounds, since no correlation is seen between a composition as claimed and amounts to be administered throughout a day. See also the new matter rejection *supra*.

Claim 1 is confusing and improper in the repetition of members of the Markush grouping such as succinate, fumarate, L-malate

Claims 23-25 are incomplete in lacking punctuation.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Mothernature.com or Whole Health Discount Center.

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The claims are directed to a composition consisting essentially of two or more chemical substances of Krebs cycle.

Each of the references teach a composition consisting essentially of calcium and magnesium citrate for oral administration. It is noted that the reference does not teach that the composition can be used for improving bioenergy metabolism, however, the intended use of the composition does not distinguish the composition since such undisclosed use is inherent in the disclosed composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus, the intended use is not limiting. "The claiming of a new use . . . which is inherently present in the prior art does not necessarily make the claim patentable." *In re Best*, 195 USPQ 430, 433 (CCPA 1977). When applicant claims a "composition in terms of function . . . and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the Examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection" (MPEP 2112).

Therefore, the reference anticipates the claims.

Claim 1 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Waterman *et al.*.

The claims are directed to a composition consisting essentially of two or more chemical substances of Krebs cycle.

Waterman *et al.* discloses a composition comprising at least two members of the citric acid (Krebs) cycle in conjunction with a food carrier containing at least vitamins and minerals. See, e.g., col. 4, lines 20-28, Trials and claims.

Therefore, the reference anticipates the claims.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants argue that the Waterman composition is not for human consumption. However, the claims are not directed to a process, but rather to a composition for which the intended use is to improve bioenergy of cells. Organisms other than humans have cells.

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In *re Herz*, 537 F.2d 549, 551 - 52, 190 USPQ 461, 463 (CCPA 1976)(emphasis in original)(Prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid "consisting essentially of" certain components. In finding the claims did not exclude the prior art dispersant, the court noted that appellants' specification indicated the claimed composition can contain any well - known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.). See also *Atlas Powder Co. v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); In *re Janakirama - Rao*, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); *Water Technologies Corp. v. Calco, Ltd.*, 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In *re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063 - 64 (Bd. Pat. App. & Inter. 1989)("Although 'consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps . . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by 'consisting essentially of' language.").

Applicant has not demonstrated with objective evidence that whey or whey permeate materially affects the basic and novel characteristics of the claimed invention.

Therefore the rejection is deemed proper and it is adhered to.

Claim 1 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Richmond *et al.*.

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The claims are directed to a composition consisting essentially of two or more chemical substances of Krebs cycle.

Richmond *et al.* discloses a composition containing members of the citric acid (Krebs) cycle in conjunction with at least magnesium and calcium. See, e.g., col. 2, line 66 through col. 3 and claim 1. The reference is suitable for consumption by cells and is in a pharmaceutically acceptable carrier.

Therefore, the reference anticipates the claims.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that the composition disclosed by the reference is not for consumption. However, the intended use of the composition as claimed is "to improve the bioenergy metabolism of cells". In any event, clearly, the composition disclosed by the reference can be consumed by microbial the cells since it contains a variety of nutrients, including albumin. Accordingly, it can reasonably be presumed that it improves the bioenergy metabolism of these cells. Applicant has not demonstrated with objective evidence that the disclosed composition does not "improving the bioenergy metabolism of cells". As to the argued carriers, the solution of the reference is in a liquid dosage form or at least is provided in a pharmaceutically acceptable carrier or means of delivery.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

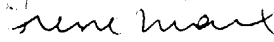
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Irene Marx
Primary Examiner
Art Unit 1651